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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/087,217 | 03/04/2002 | Yong Yao | 053735-5004-01 | 2158 |

9629 7590 12/27/2004
MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

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| EXAMINER |
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ULM, JOHN D

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| ART UNIT | PAPER NUMBER |
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1646

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/087,217 | Applicant(s) YAO ET AL. | |
| | Examiner John D. Ulm | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24,26,28-45,47,49-67,69,71 and 73-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24,26,28-45,47,49-67,69,71 and 73-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1) Claims 22 to 24, 26, 28 to 45, 47, 49 to 67, 69, 71 and 73 to 82 are pending in the instant application. Claims 22, 26, 28, 36, 40, 41, 43, 47, 49, 50, 57, 61, 62, 64, 65, 69, 71, 73 and 79 have been amended and claims 1 to 21, 25, 27, 46, 48, 68, 70, 72 and 83 to 102 have been canceled as requested by Applicant in the correspondence filed 01 October of 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4) Claims 22 to 24, 26, 28 to 45, 47, 49 to 67, 69, 71 and 73 to 82 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. A claim that fails to interrelate essential elements of the invention as described in the specification or in other statements of record is incomplete. The instant claims recite the step of "exposing the cell to at least one membrane potential dye". In the response filed 01 October of 2004 Applicant urges that the claimed method is now distinguished over the prior art because "[a]mended claims 22, 43, and 64 recite, inter alia, a method of detecting activity of a G protein-coupled receptor by expressing a G protein coupled receptor and a mutant CNG channel in a host cell and measuring the activity with at least one membrane potential dye". In that response, Applicant asserts

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that “[s]upport for amended claims 22, 43, and 64 can be found on pages 29-31 of the specification”. The only examples of an assay employing a membrane potential dye that is described therein require one to measure a “detectable change in fluorescence signal” that was generated by that dye in response to a change in the membrane potential of a cell. The instant claims do not currently reflect this distinguishing relationship because they do not recite any measuring step involving a membrane potential dye, and because claims 43 to 45, 47 and 49 to 63 are not even limited to a process that employs a G protein-coupled receptor. Whereas the claims do require one to measure an activity, they do not require the dye recited therein to be involved in any way with that measurement. Further, it is unclear how the presence of the dye is involved with the embodiments of claims 42 and 63, which appear to be drawn to an alternate embodiment of the claimed invention wherein that embodiment does not employ a membrane potential dye to measure ion flux across a biological membrane.

5) Further, Applicant is advised that it is well known in the art that most, if not all, mammalian cells express a variety of endogenous G protein-coupled receptors. It is unclear how one can attribute a measured channel activity to a specific G protein-coupled receptor, to the exclusion of all of the other G protein-coupled receptors expressed by a test cell, in the absence of a comparative step that employs a cell that is otherwise identical to the test cell except for the absence of receptor protein of interest. For instance, Example 4 of the instant application can only presume that the agonistic responses observed therein can be credited to the exogenous dopamine receptor employed in that experiment, because the experimental design does not exclude the

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very real possibility that the measured response resulted either entirely or in part from the activation of an endogenous receptor protein.

6) Applicant's arguments filed 01 October of 2004 have been considered but are moot in view of the new ground(s) of rejection.

7) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

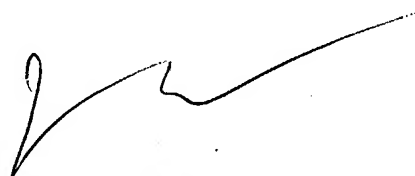
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brunmbach can be reached on (571) 272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
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